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conced.

16. (Amended) A [Composition] composition [prepared with the powder] comprising a powder according to any one of claims 1-8 or a powder [with the product] obtained by the process according to any one of claims 9-15.

17. (Amended) A [Process] process for the preparation of a dispersion of reversed vesicles in a biodegradable oil, [characterised in that] wherein the powder according to any one of claims 1-8 or the product obtained from the process according to any one of claims 9-15 is dispersed in the biodegradable oil.

### REMARKS

#### Rejection of claims 1-3 under 35 U.S.C. § 112, 1<sup>st</sup> ¶

The Office Action rejected claims 1-3 as non-enabled for other than sucrose fatty acid esters. For the following reasons, the applicants respectfully traverse this rejection.

The present inventors have surprisingly discovered that removal of apolar solvent from reversed vesicles comprising one or more non-ionic surfactants yields a powder that, when dispersed in another apolar solvent, such as a biodegradable oil, results in a secondary dispersion of reversed vesicles. The specification (p. 2, lns. 15-16) teaches that any non-ionic surfactant (which, impliedly, is capable of forming reversed vesicles can be used. Further preferred non-ionic surfactants are disclosed on p. 2, lns. 18-24, and include a variety of non-ionic surfactants other than sucrose fatty acid esters. Furthermore, many reversed vesicle forming non-ionic surfactants are known in the art (*e.g.*, WO 93/00069, as disclosed in the present specification)

The assertions of enablement within a patent application are presumptively correct, and the burden is on the Patent Office to refute:

As a matter of Patent Office practice . . . a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first

paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

...

[I]t is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

*In re Marzocchi*, 169 USPQ 367, 369-70 (C.C.P.A. 1971).

The Office Action fails to provide any scientific reasoning or evidence as to why one of ordinary skill in the art could not make and use all reversed vesicle forming non-ionic surfactants in the present invention. The Office Action merely alleges that the specification does not adequately teach what compounds can be used to form reversed vesicles and that one skilled in the art would not be able to select proper compounds to practice the invention without undue experimentation. The applicants respectfully submit that this is merely a conclusion unsupported by any scientific reasoning or evidence and, therefore, falls short of the *Marzocchi* standard.

Furthermore, the applicants emphasize that the claimed invention **is not** a reversed vesicle made of one or more non-ionic surfactants. Such reverse vesicles are well known in the art. Rather, the claimed invention is a **powder** of non-ionic surfactant reverse vesicles obtained by removing the apolar solvent in which the vesicles were formed. The present inventors surprisingly found that such a powder of vesicles can be re-dispersed in an apolar medium (*e.g.*, a biodegradable oil) with high yield. It would be clear to one of ordinary skill in the art that any art-recognized reverse vesicle forming non-ionic surfactant could be used in the present invention. Absent clear scientific reasoning or evidence to the contrary, the claims must be considered enabled for their full scope.

In view of the foregoing, therefore, the applicants respectfully request reconsideration and withdrawal of this § 112, 1<sup>st</sup> ¶ rejection.

### Rejection of claims 1-3 under 35 U.S.C. § 103

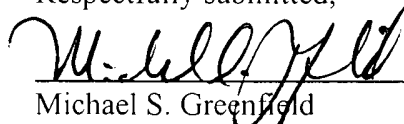
Claims 1-3 were rejected as obvious over EP 0 521 562, in view of EP 0 678 295, EP 0 159 237, and GB 2002319 alone or in combination. The Office Action alleged that EP 0 521 562 taught reversed vesicles of the present invention and the remaining art taught reducing liposomes and micelles to powder form. The Office Action concluded it would have been obvious to reduce the reversed vesicles of the EP 0 521 562 to powder form. For the following reasons, the Applicants respectfully traverse.

A surprising feature of the present invention nowhere taught, suggested, or contemplated by any of the art is that the presently claimed reversed vesicle powder, when dispersed in an apolar vehicle such as a biodegradable oil, retains its vesicular structure with a yield much greater than compared to that when the reversed vesicles are prepared directly in the biodegradable oil. Because the prior art does not suggest this surprising property of the claimed compositions, it cannot render them obvious. *In re Papesch* 137 USPQ 43 (C.C.P.A. 1963); MPEP 2144.09. Accordingly, reconsideration and withdrawal of this § 103 rejection is respectfully requested.

If there are any questions or comments regarding this Response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

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Respectfully submitted,

  
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